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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,462	05/08/2001	Robert Ian Lechler	2292/OH795	8594

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EXAMINER	
OUSPENSKI, ILIA I	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,462	LECHLER ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *17,27 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-16, 18-26, 29, 30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's Preliminary Amendments 10/30/2000 and 10/28/2003 are acknowledged and entered. Claims 29 and 30 have been added.

Claims 1 – 30 are pending.

Claims 17, 27, and 28 are withdrawn from consideration by the Examiner as drawn to non-statutory subject matter. "Use" claims are non-statutory under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki, 153 USPQ 678 (Bd. App. 1967) and Clinical Products, Ltd v. Brenner,255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). See MPEP 2173.05(q).

Claims 1 – 16, 18 – 26, 29, and 30 are under consideration and being acted upon.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However the specification discloses a number of sequences without the appropriate sequence identification (e.g. see page 12). Therefore, it is not readily apparent that the instant application is in compliance with the sequence rules. Applicant is required to clarify whether sequence listing in the Computer Readable Form and paper copy provide for each sequence disclosed in the specification.

Applicant is reminded of the sequence rules which require a submission for all sequences of 10 or more nucleotides or 4 or more amino acids (see 37 CFR 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules. Applicant is required to reference each sequence in the claims and the specification by use of the appropriate sequence identifier. See 37 CFR 1.821 and MPEP 2422.

3. The following is noted: Claims 1 and 2 encompass biological reagents and methods that comprise or utilize different products: CTLA-4 and fusion proteins thereof; antibodies to CTLA-4 and other proteins which bind to CTLA-4; and cells or tissues which express MHC II molecules. Fusion proteins, antibodies, cells and tissues differ with respect to their structure, and in mode of action.

Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

4. It is noted that for prosecution purposes, a "membrane-associated protein which can bind to CTLA-4" is assumed to comprise an antibody to CTLA-4, as disclosed in the Specification on page 5, lines 19 – 21. Should additional species of "membrane-associated proteins which can bind to CTLA-4" be introduced during prosecution, these would be subject to further restriction requirement.

Restriction

5. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I: Claims 1, 5, and 6, drawn to a biological reagent capable of inhibiting transplant rejection, as it reads on the CTLA-4 protein.

Group II: Claims 2 – 4, drawn to methods of inhibiting transplant rejection by soluble CTLA-4.

Group III: Claim 7, drawn to a nucleic acid encoding CTLA-4.

Group IV: Claims 1, 8, 9, and 16, drawn to a biological reagent which is a membrane-associated proteins which bind to CTLA-4, as it reads on an anti-CTLA-4 antibody.

Group V: Claims 10 and 30, drawn to a nucleic acid encoding a CTLA-4 binding protein, as it reads on an anti-CTLA-4 antibody.

Group VI: Claim 11, drawn to a cell expressing a CTLA-4 binding protein, as it reads on an anti-CTLA-4 antibody.

Group VII: Claims 12 and 29, drawn to a tissue expressing a CTLA-4 binding protein, as it reads on an anti-CTLA-4 antibody.

Group VIII: Claim 13, drawn to an animal containing a cell expressing a CTLA-4 binding protein, as it reads on an anti-CTLA-4 antibody.

Group IX: Claim 14, drawn to a method of transplantation using tissue expressing a CTLA-4 binding protein, as it reads on an anti-CTLA-4 antibody.

Group X: Claim 15, drawn to a method of preparing tissue for transplantation such that it expresses a CTLA-4 binding protein, as it reads on an anti-CTLA-4 antibody.

Group XI: Claims 1, 18 – 21, and 26, drawn to a cell expressing on its surface MHC class II molecules of a different organism.

Group XII: Claim 22, drawn to a biological tissue expressing on its surface MHC class II molecules of a different organism.

Group XIII: Claim 23, drawn to an animal containing a tissue expressing on its surface MHC class II molecules of a different organism.

Group XIV: Claim 24, drawn to a method of transplantation using a tissue expressing on its surface MHC class II molecules of a different organism.

Group XV: Claim 25, drawn to a method of preparing tissue for transplantation such that it expresses MHC class II molecules of a different organism.

6. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

As was also found in the International Search Report, the Invention of Group I was found to have no special technical feature that defined the contribution over the prior art of Lenschow et al. (IDS #6) and/or Cohen et al. (Science 1992 v.257, p.751).

The references teach CTLA-4 fusion proteins as reagents capable of inhibiting T-cell mediated transplant rejection, thus anticipating at least claims 1, 5, and 6.

Since Applicant's Inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

7. Applicant is invited to amend the claims or provide new claims which read on each Group I – IV separately.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
Tech center 1600
6/24/04

ILIA OUSPENSKI

Patent Examiner

Art Unit 1644

June 22, 2004